PB90-260431

Dicofol: Position Document 4. Intent to Cancel Registrations of Pesticide Products Containing Dicofol; Denial of Applications for Registration of Pesticide Products Containing Dicofol Conclusion of Special Review; Notice of Final Determination

(U.S.) Environmental Protection Agency, Washington, DC

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This Position Document addresses the risks and benefits of pesticide products containing the subject active ingredient. The Agency has determined that the use of products containing the subject active ingredient may meet or exceed a risk criterion described in 40 CFR Part 154. Potential hazards will be examined further to determine the nature and extent of the risk, and considering the benefits of the subject active ingredient, whether such risks cause unreasonable adverse effects on the environment.

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Part VII

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Dicofol; Intent To Cancel Registrations of Pesticide Products Containing Dicofol; Denial of Applications for Registration of Pesticide Products Containing Dicofol; Conclusion of Special Review; Notice of Final Determination PD-4

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30000/37c; FRL-3023-5]

Dicofol; Intent To Cancel Registrations of Pesticide Products Containing Dicofol; Denial of Applications For Registration of Pesticide Products Containing Dicofol; Conclusion of Special Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Final Determination.

SUMMARY: EPA initiated a Special Review to consider whether the pesticide registrations for all registered uses of dicofol should be modified or cancelled. This was published in the **Federal Register** of March 21, 1984 (49 FR 10569). The Special Review was initiated because EPA believed that there were substantial risks to the environment associated with the presence of DDT and related impurities (DDTr) as contaminants of technical dicofol. EPA also expressed concern about the possible oncogenicity of dicofol. In the **Federal Register** of October 10, 1984 (49 FR 39820), EPA announced the availability of Position Document 2/3 (PD 2/3) and its proposed decision to cancel registrations of pesticide products containing dicofol. EPA issued in the **Federal Register** of August 15, 1985 (50 FR 33008), an amended notice proposing to allow the continuation of the registrations of pesticide products containing dicofol if a number of modifications to the registrations were implemented. This proposal was based upon new information received by EPA concerning the registrants' proposal to lower the DDTr contamination levels in their technical products and EPA's conclusion that there is limited evidence that dicofol poses an oncogenic risk to humans through dietary and worker exposure. This notice concludes the Special Review and announces EPA's final decision to cancel registrations and deny applications of all pesticide products containing dicofol unless certain modifications are made to the pesticide product registrations.

DATE: Requests for a hearing by a registrant, applicant, or other adversely affected person must be received by June 30, 1986 or, for a registrant or applicant, within 30 days from their receipt by mail of this notice, whichever date is the later applicable deadline.

ADDRESSES: Requests for a hearing must be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: By mail: Bruce Kapner, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Office location and telephone number: Rm. 711, Crystal Mall Building #2, 1921 Jefferson Davis Highway, Arlington, VA, (703-557-3262).

SUPPLEMENTARY INFORMATION: This notice is organized into six units. Unit I is the Introduction. Unit II describes the legal framework within which this notice is issued. Unit III sets forth EPA's assessment of the risks and benefits associated with the continued use of dicofol products. Unit IV sets forth the regulatory actions required by this notice. Unit V contains the comments of the Secretary of Agriculture, the Scientific Advisory Panel, and other public comments and EPA's response to those comments. Unit VI provides a brief discussion of the procedures which will be followed in implementing the regulatory actions which EPA is announcing in this notice.

I. Introduction

A. Notice of Special Review

Notice of the initiation of the Special Review (formerly called the Rebuttable Presumption Against Registration (RPAR) process) was published in the **Federal Register** of March 21, 1984 (49 FR 10569). That notice was based on the concern that dicofol is contaminated with DDT, DDE, and/or closely related compounds (collectively referred to as DDTr) that can cause significant adverse effects on nontarget wildlife. EPA had concluded that pesticide products containing dicofol met one of the risk criteria for intensive review of the risks and benefits to determine whether continued registration would cause unreasonable adverse effects on the environment. Accordingly, a Special Review was initiated for all registered pesticide products containing dicofol. The notice also noted that dicofol had induced liver tumors in a National Cancer Institute (NCI) bioassay in mice, but that EPA had not been able to validate the study at that time.

B. Preliminary Notices of Intent to Cancel

After reviewing comments received on the March 21, 1984 notice, EPA issued a preliminary notice of intent to cancel registrations of pesticide products containing dicofol which was published in the **Federal Register** of October 10, 1984 (49 FR 39820). In that notice, EPA proposed cancellation of all uses of dicofol based on the ecological risks posed by the DDTr contaminants in dicofol. EPA stated that cancellation was consistent with the recommendation contained in a Biological Opinion issued by the Office of Endangered Species which concluded that continued use of dicofol was likely to jeopardize the continued existence of the endangered peregrine falcon. EPA also expressed its concern that a study from the National Cancer Institute (NCI) suggested that dicofol produces tumors in test animals. However, EPA did not evaluate the oncogenic risk to humans because the NCI bioassay on dicofol still had not been validated.

In response to this notice, registrants of dicofol products informed EPA that they would be able to manufacture products containing substantially lower levels of DDTr. They indicated that approximately 2 years after EPA's final decision in the Special Review they could produce commercial quantities of technical dicofol that contained 0.1 percent or less DDTr contamination. They further indicated that they were currently producing, or would shortly be able to produce, technical dicofol with DDTr contamination levels substantially below those reported in their Confidential Statements of Formula on file with EPA.

EPA reviewed the registrants' proposal to lower the DDTr contamination of technical dicofol and, while it did not conclude that the lower levels of DDTr were free from risk, it concluded that such reductions would qualitatively reduce risks of adverse effects to nontarget organisms to a level where the benefits would exceed the risks.

The Scientific Advisory Panel (Panel) reviewed EPA's earlier notice of preliminary determination, the supporting Position Document 2/3, and the registrants' proposal to reduce the level of DDTr contaminants. The Panel concurred with EPA's conclusion that the risks would be less from the 0.1 percent DDTr contamination level than from the current DDTr levels in dicofol products.

In addition, after the October 10, 1984 notice, EPA received information regarding the validity of the NCI oncogenicity study. EPA originally considered the NCI study to be invalid due to reported decomposition of the test material during the test period. However, NCI informed EPA that subsequent chemical analysis of the archived test material showed that it was representative of technical dicofol, and that there was no evidence of decomposition. Based on this information, EPA concluded that the NCI bioassay was valid.

On August 15, 1985, EPA issued a notice that revised and expanded the October 10, 1984 notice and presented EPA's revised assessment of the risks, including for the first time a discussion of the possible oncogenic risk to humans, and benefits of using dicofol (50 FR 33008). Additionally, this notice set forth a new set of proposed regulatory actions. EPA concluded that implementation of the registrants' proposal to lower the DDTr contamination of technical dicofol would reduce the risks of adverse effects to nontarget organisms to a level where the benefits would exceed the risks.

The Panel reviewed that notice and concluded that the evidence that dicofol is a potential human carcinogen was weak and that a quantitative risk assessment could not be justified. The full text of the Panel's comments and EPA's response to those comments are found in Unit V.

C. Consultation with the Office of Endangered Species

As required by regulation, EPA initiated consultation with the Office of Endangered Species (OES) in March 1984, concerning the effects of dicofol on endangered species. OES responded in August 1984, that the use of dicofol is likely to jeopardize the continued existence of the two subspecies of peregrine falcon.

When EPA proposed to allow registrations of dicofol products to continue, provided that the level of DDTr contamination was significantly reduced, it reinitiated consultation with OES concerning the effects of this proposal on the endangered peregrine falcon. OES responded in November 1985, stating that use of dicofol contaminated with 0.1 percent or less DDTr would not be likely to jeopardize the endangered peregrine falcon, but that, based on available information, use of dicofol products with higher levels of DDTr still appeared likely to jeopardize the continued existence of the peregrine. Accordingly, OES recommended that EPA immediately prohibit further use of dicofol products, confiscate all existing stocks of dicofol products, and prohibit manufacture of dicofol containing more than 0.1 percent DDTr.

In December 1985, EPA requested OES to reconsider the November 1985 Biological Opinion in light of information concerning the amount of DDTr added to the environment from the use of dicofol during the period before the registrants were able to commence production of dicofol containing 0.1 percent or less DDTr.

In March 1986, OES issued a revised Biological Opinion which, consistent with earlier opinions, found that dicofol contaminated with DDTr at levels greater than 0.1 percent jeopardized the continued existence of the peregrine falcon, but that use of technical dicofol with levels of DDTr at 0.1 percent or less would not jeopardize the peregrine. OES further stated that reasonable and prudent alternatives existed to permit the use of dicofol products that would not jeopardize the peregrine. In all parts of the United States except California, OES indicated that jeopardy to the peregrine could be avoided by reducing the level of DDTr contamination in technical dicofol to 0.1 percent or less no later than December 31, 1988, after which only dicofol products containing 0.1 percent or less DDTr could be sold.

OES concluded that the situation in California warranted a different course of action. OES listed two reasonable and prudent alternatives: (1) the use and sale of all dicofol products containing greater than 0.1 percent DDTr should be banned immediately, or (2) to compensate for the negative effects of the use of dicofol during the period before all products containing more than 0.1 percent DDTr are prohibited in channels of trade, dicofol manufacturers should be required to fund a portion of the nest manipulation work of the Santa Cruz Predatory Bird Research Group (SCPBRG). The next manipulation work is a high priority of the U.S. Fish and Wildlife Service Recovery Plan for the Pacific States Population of the Peregrine Falcon, and scientific authorities agree that this work is vital to the continued existence of this population. Peregrine falcons in central coastal California experience complete reproductive failure because their eggs break before hatching due to thinned eggshells caused by DDE. To aid the recovery of the Pacific States Population, SCPBRG removes eggs laid in the wild, artificially incubates and hatches them, and releases the hatchlings back into nests of wild peregrines. The nest manipulation work of SCPBRG has been highly successful in supplementing population size but has not been operating at full capacity due to limited funding. Funds paid by dicofol manufacturers will be used to hatch artificially eggs from nests located in areas of California subjected to DDE residues from dicofol. Program personnel indicate that $25,000 for 1986 and $75,000 for each of the following 4 years would enable SCPBRG to manipulate enough nests to largely offset the reproductive failure in peregrines that is due to DDE. The need for funding for 5 years is not based on time to absolutely remove DDE residues in California, but upon estimates of time required to build up breeding numbers such that enough wild peregrines are reproducing at a level sufficient to sustain the Pacific population naturally. OES also indicated that the sale of dicofol products containing more than 0.1 percent DDTr contamination should be prohibited in California after December 31, 1988.

In addition to the threat to the population of peregrines in California, OES expressed concern for the peregrine falcon populations in New Mexico and Texas, the brown pelican, bald eagle, Everglade kite, wood stork, and Arctic peregrine falcon. While OES did not conclude that the survival of these other endangered species and populations is threatened by use of dicofol with greater than 0.1 percent DDTr contamination, OES did request an expedited phase-out because the rate of recovery for these species may be affected. The finding of no jeopardy but that use of dicofol with greater than 0.1 percent DDTr contamination may affect the recovery rate is partially based upon the generally improved reproductive success exhibited by these species and by the consideration of the amounts of DDTr that would be added to these species' environments during an expedited phase-out. Accordingly, OES recommended that EPA schedule the phase-out as expeditiously as possible to minimize the hazards to these other endangered species.

Following issuance of the March 1986 Biological Opinion, on March 28, 1986, EPA met with representatives of Rohm and Haas Company and Makhteshim-Agan, Inc., the two registrants currently producing technical or manufacturing-use dicofol products. Representatives from the National Audubon Society, National Wildlife Federation, and Natural Resources Defense Council also attended the meeting. The representatives of the producing companies agreed to provide funds for the nest manipulation program as described in the OES opinion.

Subsequent to the March 28, 1986 meeting, EPA received letters from the three environmental organizations present at the meeting. The letters all expressed opposition to, in essence, EPA's allowing a "penalty" to be paid by dicofol manufacturers in return for a "permit" to continue environmental contamination. The letters noted that endangered species other than the peregrine falcon will suffer from the use of dicofol and gain no benefit from funds paid to aid a population of a single endangered species. The environmental

groups opposed the continued use of dicofol containing any amount of DDTr, and noted that dicofol itself may pose environmental risk.

Neither EPA nor OES views the mitigation of jeopardy by payment to SCPBRG as a "permit" to contaminate the environment, but rather as an efficacious and responsible course to aid the peregrine falcon in California and hasten the removal from the environment of residues of DDTr from dicofol containing greater than 0.1 percent DDTr. With regard to other endangered species, EPA accepts OES's opinion that the expedited phase-out will not threaten the survival of the other species.

EPA makes no conclusion that dicofol containing 0.1 percent DDTr contamination is free from risk, but only that the environmental risk from the reduction to 0.1 percent DDTr or less by December 31, 1988, is offset by the benefits to the general population. Further, EPA shares the concerns that dicofol itself may pose an environmental hazard and is requiring that additional data on this concern be submitted on an expedited basis. However, EPA believes that the data available at this time on dicofol itself are inconclusive.

D. Special Review Docket and Public Comments

In addition to the comments from OES, USDA, and the Panel, public comments were also submitted on the August 1985 preliminary notice of intent to cancel and were carefully considered by EPA in the development of this final determination, and certain changes were made in this decision based on the comments. The comments received in response to the Position Document 2/3 and changes in the final decision are discussed in detail in Unit V.

Further, on several occasions EPA met with or corresponded with various interested parties. Summaries of these meetings and copies of this correspondence are contained in a docket maintained for this Special Review, as provided in EPA's Special Review regulations published in the **Federal Register** of November 27, 1985 (50 FR 49003).

The docket is available for public inspection from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays, in: Rm. 236, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

It must be noted that portions of the docket are considered Confidential Business Information and are not available for public inspection.

II. Legal Background

In order to obtain a registration for a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), an applicant for registration must demonstrate that the pesticide satisfies the statutory standard for registration. That standard requires, among other things, that the pesticide perform its intended function without causing "unreasonable adverse effects on the environment," under FIFRA sec. 3(c)(5). The term "unreasonable adverse effects on the environment" is defined under FIFRA sec. 2(bb) as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." This standard requires a finding that the benefits of the use of the pesticide exceed the risks of use, when the pesticide is used in compliance with the terms and conditions of registration or in accordance with commonly recognized practice.

The burden of proving that a pesticide satisfies the standard for registration rests on the proponents of registration and continues as long as the registration remains in effect. Under section 6 of FIFRA, the Administrator may cancel the registration of a pesticide or require modification of the terms and conditions of registration whenever it is determined that the pesticide appears to cause unreasonable adverse effects on the environment.

In determining whether the risks of a registered pesticide outweigh its benefits, EPA considers both possible changes to the terms and conditions of registration which can reduce risks as well as the impacts of such modifications on the benefits of use. If EPA determines that such changes reduce risks to the level where the benefits outweigh the risks, it may require that they be made.

Alternatively, EPA may determine that no change in the terms and conditions of a registration will adequately assure that use of the pesticide will not pose unreasonable adverse effects. In that event, the Administrator may issue a notice of intent to cancel the registration or to hold a hearing to determine whether it should be cancelled under FIFRA sec. 6(b). In determining whether to issue such a notice, the Administrator must take into account the impact of the action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days before formally issuing such a notice, he must inform the Secretary of Agriculture in writing of the substance of the proposed actions and supply the Secretary with an analysis of the expected impact on the agricultural economy. At the same time, under FIFRA sec. 25(d), the Administrator is required to submit the proposal to the Panel for comment as to the impact on health and the environment of the action proposed in the cancellation notice. EPA is also required by law, where appropriate, to consult with the U.S. Department of the Interior's Office of Endangered Species to see if the proposed action may affect an endangered species.

EPA also follows a practice of informing the public of its proposals to issue cancellation notices so that registrants and other interested persons can also comment or provide relevant information before any final Notice of Intent to Cancel is issued. Registrants and other interested persons are invited to review the data upon which the proposal is based and to submit data and information to address whether EPA's initial determination of risk was in error. In addition to evidence relating to risk, comments may include evidence as to whether any economic, social and environmental benefits of use of the pesticide outweigh the risks of use.

If, after reviewing the comments received, EPA decides to issue a Notice of Intent to Cancel dicofol products, any adversely affected person may request a hearing to challenge the action. In the hearing, any party opposing cancellation would have an opportunity to present data, witness testimony, and other evidence to show that the registrations of the pesticide should be permitted to continue. Other interested parties could intervene to present evidence in favor of cancellation. At the end of the hearing EPA would decide on the basis of the evidence presented whether or not to cancel or restrict the registration of pesticide products. If no hearing is requested, each registration would be cancelled by operation of law 30 days after receipt by the registrant or publication in the **Federal Register** of the final notice, which ever occurs later.

III. Summary of Risk and Benefit Determinations

A. Risks of Adverse Effects on Wildlife

EPA's principal concern with the continued use of dicofol as currently manufactured is that nontarget wildlife, particularly endangered species, may be adversely affected by the DDTr in dicofol products, and that dicofol itself may affect avian reproduction.

1. *Composition of dicofol products.* All dicofol products contain as impurities a

group of chemically similar compounds including the o,p' and p,p' isomers of DDT, DDE, DDD, and of a chemcial referred to as extra-chlorine DDT (C1-DDT). In C1-DDT, a chlorine atom substitutes for the hydrogen atom on the ethane moiety of DDT or the hydroxy group on the ethane moiety of dicofol. These DDT-related substances are collectively referred to as DDTr. The total amount of DDTr in different producers' dicofol products varies and the proportions of the different impurities comprising the DDTr portion also vary. Because the specific amounts and proportions of the DDTr compounds in the producers' products are considered trade secret or confidential business information, they are not being presented here. In the analyses used as the basis of the October 1984 proposed cancellation notice, EPA assumed that DDTr impurities constituted 10 percent of technical grade dicofol, which was a reasonable approximation of the amount of DDTr found in their registered technical dicofol products at that time. Subsequently, some dicofol registrations have been amended to indicate that DDTr constitutes no more than 2.5 percent of the technical dicofol in the product.

2. *Avian toxicity of DDTr.* The conclusion that dietary exposures to DDTr at levels below 1 part per million (ppm) would have significant adverse effects on avian reproduction is supported by a substantial body of laboratory and field data. Although DDE interferes with many aspects of avian reproduction, the best characterized effect is eggshell thinning which causes the eggs to break prematurely, interferes with gaseous exchange, and in other ways reduces the number of chicks being hatched. While field monitoring studies lack controlled or precisely known exposure information, they provide important indications of the dietary concentrations of DDE that are toxic to birds. Bald eagles, for instance, in Maine during the 1960s and 1970s experienced eggshell thinning and significantly impaired reproduction. During this same time period, DDE residues in eels and fish, which comprise 90 percent of the bald eagle diet in Maine, were below 0.3 ppm. Other data suggest that eastern brown pelicans may be producing thinner eggshells from feeding on food possibly containing as little as 0.1 ppm DDE. In Australia, monitoring of peregrine falcons found an average of 0.11 ppm DDE in the prey species, and eggshells were 20.4 percent thinner than those from the years prior to use of DDT. Other information on California brown pelicans supports similar inferences.

Laboratory studies have demonstrated that dietary exposure of birds to DDE at low levels, often in the 0.6 ppm to 3.0 ppm range, will cause significant thinning of eggshells. Effects have been experimentally demonstrated in a wide variety of species: Mallard, black duck, ring dove, American kestrel, barn owl, and screech owl.

Taken collectively, EPA finds that this body of information supports a conclusion that dietary exposure to DDE at levels lower than 1.0 ppm will cause significant adverse effects on reproduction in some avian species. Moreover, there is considerable scientific uncertainty concerning "no-effect" levels and the continuing reproductive problems in some wild populations as a result of exposure to DDTr. A "no-effect" level for eggshell thinning has not yet been established.

3. *Fish toxicity of DDTr.* Exposure of fish to DDT or DDE-contaminated food or water can interfere with fish reproduction. Studies have shown a correlation between the reproductive failure of sea trout and DDT residues in menhaden, a fish species that is a major source of food for sea trout. Flounder eggs in seawater containing 2 parts per billion (ppb) DDT showed abnormal development, and 39 percent of the exposed larvae had vertebral deformities at hatching.

4. *Environmental levels of DDTr.* Nationwide, levels of DDT and related compounds have generally declined since the 1972 cancellation of pesticide registrations of DDT products. The most recent monitoring data suggest, however, that DDE residues in freshwater fish, currently about 0.4 ppm, may have stabilized or are declining more slowly. A similar trend may be emerging for DDE residues in starlings, which presently average about 0.15 ppm. Likewise, although DDE residues in the wings of mallards and black ducks have declined since 1969, none of those decreases after 1976 has been statistically significant. Furthermore, the residues of DDE in ducks from the Pacific Flyway States (California, Colorado, Oregon, Arizona, and New Mexico) actually increased.

In addition to examining national trends, EPA analyzed monitoring data from four States in which large amounts of dicofol are used: California, Arizona, Texas, and Florida. More than 70 percent of all dicofol used is applied in these States. The use of dicofol is further concentrated in certain regions of these States. In these regions, levels of DDE are generally higher than in the rest of the country and these residues may exceed levels known to cause adverse effects on avian and fish reproduction.

5. *Dicofol's contribution to ambient DDTr residues.* Using a variety of approaches, EPA has determined that use of dicofol products contaminated with DDTr at levels approximately equal to a tenth of the active ingredient content would contribute significantly to the overall burden of DDT and related compounds in the environment.

One approach calculated the amount of DDTr added to the environment based on the total amount of dicofol applied. Approximately 1 million pounds of dicofol active ingredient are applied annually in California, and assuming 10 percent contamination with DDTr, this is equivalent to 100,000 pounds or 50 tons of DDTr yearly. Making the same assumption, the estimated annual contributions of DDTr for Arizona, Texas, and Florida are 12,600 pounds, 15,400 pounds, and 85,700 pounds, respectively.

EPA recognizes that much of the DDE detected in the environment in recent years is the result of the gradual dissipation of DDT pesticides applied prior to their cancellation in 1972. To evaluate the relative contributions of pre-1972 use of DDT and past and current use of dicofol, EPA prepared a mass-balance analysis for Kings County in the San Joaquin Valley of California. Assuming that dicofol use will not increase and other assumptions detailed in PD 2/3, the analysis demonstrated that, by 1984, a reasonable estimate of the environmental loading of DDTr from pre-1972 use of DDT was about 850,000 pounds in comparison to 200,000 pounds attributed to the use of dicofol. By the year 2000, EPA's analysis predicts that total environmental loading of DDTr would be about 450,000 pounds with continued use of dicofol with contamination of 10 percent DDTr, versus only 220,000 pounds if the use of dicofol ceased in 1984. In short, if EPA were to permit the continued use of dicofol at 1984 contamination levels, the residues of DDTr in the environment in the year 2000 could be almost twice as high as if dicofol use were prohibited.

EPA has also used other models to estimate the ambient environmental concentrations of DDTr that would result solely from use of dicofol assuming an average of 10 percent DDTr in the technical dicofol. EPA used a mathematical model to estimate the concentration of DDTr from dicofol use in the water of the Arroyo Colorado River in southern Texas. This model predicts that residues in the river system could stabilize eventually (reach

equilibrium) at approximately 9 parts per trillion (ppt). This concentration in water would result in DDTr residues of about 9 ppm in fish, a level harmful both to the fish and to fish-eating birds.

In addition, based on physical and chemical principles, EPA estimated that use of dicofol on cotton and other crops in Kings County, California, might result in food chain contamination at levels that would be likely to affect avian species adversely. Specifically, EPA predicted that migrating waterfowl could feed on chironomid midge larvae contaminated with as much as 1.4 ppm DDTr. Neither model assumed any other source of DDTr; adding in background levels of DDTr from pre-1972 DDT use would increase the amount of DDTr expected in the food chain.

6. *Risks of dicofol and its metabolites.* In addition to the considerable information on the risks to the environment posed by the DDTr contaminants in dicofol, a small body of data suggests that dicofol, itself, may adversely affect avian reproduction. Although the mechanism is not clear, it appears either that dicofol may be metabolized by some avian species to DDE or that dicofol, itself, may cause eggshell thinning. If either mechanism exists, then environmental residues of dicofol may pose a risk to nontarget wildlife, in addition to the risk attributable to the DDTr contamination of dicofol products.

The available data on the metabolism of dicofol do not definitively resolve the issue of whether dicofol residues are converted to DDE in animals. Each of the studies supporting such a conclusion is also susceptible to other interpretations. For example, in studies performed by different laboratories, dicofol with a known level of DDT contamination was fed to bobwhite quail and mallard ducks. For both species, test animals had levels of DDE residues higher than could be explained by the levels of DDE contaminants present in the dicofol. The researchers speculated that some of the dicofol was converted to DDE by the test birds. One dicofol registrant has suggested, however, that the elevated levels of DDE resulted not from the metabolism of dicofol by the test animals, but rather from the conversion, during the chemical analysis of the test animals' tissues, of residues of C1-DDT to DDE. No experimental data are available to prove or disprove the registrant's hypothesis. In another study, rats were intubated with a corn oil solution reportedly containing "pure" dicofol. DDE was subsequently found in all tissues except the blood and brain. Because the purity of the dicofol was not reported and no samples of the test material are now available for analysis, it is now impossible to determine whether the DDE residues came from DDTr contamination or the "pure" dicofol.

On the other hand, a preliminary report on dicofol metabolism in chickens shows no increase in levels of DDE above what would be expected from the presence of DDTr in the test material. Based on the preliminary report, EPA has many questions about the methodology and results of this study. EPA also questions whether a metabolism study in chickens is useful in assessing the likely metabolic fate of dicofol in other avian species, since gallinaceous birds (e.g., chickens) are known to be relatively insensitive to the effects of DDT and DDE compared to nongallinaceous birds (e.g., peregrine falcons).

The concern that dicofol itself thins eggshells is based upon the structural similarity of the dicofol molecule to DDE and upon information from two studies currently underway. Because the studies have not been completed and their methodology and conclusions have not been subjected to external peer review, EPA believes that it would be premature to rely heavily on these studies as the basis for regulatory action.

The difficulty of assessing the environmental risks of dicofol, apart from its DDTr contaminants, is made even more difficult because of the relatively small amount of information available on the residue levels of dicofol in the environment. EPA will require avian reproduction and metabolism studies, conducted with sensitive species, to address the issue of the effects of dicofol and its metabolites on avian reproduction. Additionally, EPA will require widespread environmental residue monitoring to determine the exposure levels of dicofol and its metabolites. While EPA is seeking more information on the extent of this risk, the possibility that dicofol may be metabolized to DDE in animal species or that dicofol thins eggshells remain serious concerns.

7. *Distribution of sensitive species in areas with high levels of use of dicofol.* As the last element of its analysis of the environmental risks of using dicofol, EPA investigated whether species sensitive to the adverse effects of dicofol were found in areas where use of dicofol has been concentrated. This investigation revealed that one or more highly sensitive species is present in each of the major use areas for dicofol, and that several are officially designated as endangered species by the Federal Government. In particular, the March 1986 OES Biological Opinion discussed several populations of endangered species that may be affected adversely by continued use of dicofol.

Of paramount concern was the endangered peregrine falcon in California (see Unit I above), but OES also stated that use of dicofol with levels of DDTr in excess of 0.1 percent raised concerns about peregrines in the Guadalupe Mountains of southeastern New Mexico because this population was experiencing reproductive failure and could be exposed to DDTr by feeding on prey species that migrate though areas of heavy dicofol use. OES also raised concern about the impact of heavy dicofol use in south Texas on brown pelicans in the Laguna Madre. OES noted that the brown pelicans, bald eagles, Everglade kites, and wood storks could be adversely affected by dicofol use in Florida. Finally, Arctic peregrine falcons could be exposed to contaminated prey while migrating through California, Florida, and the Texas Gulf Coast.

8. *Risk conclusions.* DDT and DDE are highly persistent, bioaccumulative compounds which are toxic to birds and fish. Avian species have been adversely affected by dietary exposure to DDE at levels below 1.0 ppm. Fish have also been adversely affected at exposure levels as low as 2 ppb DDT. Because of the chemical similarities between DDT and DDE and the other constituents of DDTr, EPA believes that there is a reasonable basis for assuming that these other DDTr substances have similar properties.

Further, EPA has determined that dicofol use is concentrated in areas where levels of DDE (from all sources) are presently high enough to impair both avian and fish reproduction and that these areas are inhabited by a number of sensitive, endangered species whose continued existence could be adversely affected by exposure to current levels of DDE. EPA also believes that DDTr contamination of current dicofol products is sufficiently high to make significant contributions to the overall levels of DDE and DDT in the above major use areas. This contribution would likely result in a slowing of the decline of DDTr residues in areas of dicofol use and would likely result in a stabilization of DDTr residues at levels which would continue to cause adverse effects in wildlife. Although some data suggest dicofol itself may thin eggshells and/or may be converted to DDE in animals and thus add to the risks associated with DDTr contaminants.

EPA lacks sufficient information to evaluate this possible risk.

Consequently, EPA concludes that the continued use of dicofol as currently formulated would adversely affect nontarget wildlife. This conclusion is consistent with Biological Opinion recently issued by OES that continued use of dicofol products at current levels of DDTr contamination is likely to jeopardize the continued existence of the endangered peregrine falcon and may adversely affect other endangered species (see Unit I above).

9. *Additional data requirements.* As discussed previously, the structural similarity of dicofol to DDT, the results of several wildlife studies, and monitoring data from areas of high dicofol use suggest the possibility of metabolic conversion of dicofol to DDTr or DDE. EPA is further concerned that dicofol may directly impair wildlife reproduction. These possibilities cannot be evaluated until data are available on the metabolism and effects of dicofol *in vivo*.

Although the dicofol registration standard required reproduction studies with bobwhite quail and mallard ducks, life-cycle studies of warm and cold water fish, and aquatic organism accumulation tests, additional data are needed. The studies required by the Registration Standard provide much useful data concerning the effects of dicofol, but the tests are not sufficient to address potential metabolic conversion of dicofol to DDTr or DDE or direct effects of dicofol itself. Expansion of the fish and aquatic accumulation studies to include residue analysis will partially resolve the data gaps. In the case of avian testing, however, EPA has concerns for the special sensitivity and vulnerability of raptors and other predatory birds. Therefore, EPA is requiring a reproduction and *in vivo* metabolism/residue test employing a minimum of two representative carnivorous and/or insectivorous bird species. The two test species must include one Passeriformes species (i.e., shrike or blue jay), and one species from either the Falconiformes or Strigiformes orders (i.e., hawks, falcons (e.g., kestrels), vultures, and owls).

These new tests replace the reproduction studies on the bob white quail and mallard duck required in the Registration Standard. The new tests are required on an expedited schedule and, when received by EPA, will be used to determine if dicofol itself, or dicofol with 0.1 percent DDTr contamination, poses an environmental risk. EPA will conduct a new hazard assessment employing these data, and will determine if further regulatory action is needed to protect endangered species and other fish and wildlife species.

B. Risk of Oncogenic Effects in Humans

1. *Introduction.* An oncogenic risk assessment generally consists of a qualitative hazard assessment, a dose-response assessment, an exposure assessment, and an overall characterization of the risk. Specific guidance for conducting risk assessments for cancer is found in EPA's "Proposed Guidelines for Carcinogen Risk Assessment," published in the **Federal Register** of November 23, 1984 (49 FR 46294).

For oncogenicity, the hazard assessment includes an examination of the available scientific data (e.g., long-term animal bioassays, short-term mutagenicity studies and any human data) to evaluate the weight of the evidence regarding the chemical's human oncogenic potential. The dose-response assessment includes mathematical modeling of experimental data to estimate the chemical's potency for inducing an oncogenic response, assuming that the chemical is, in fact, a human oncogen. The exposure assessment estimates the extent to which human populations are exposed to the chemical. In the case of dicofol, this exposure is to the general public through dietary intake, to applicators during mixing and application of the pesticide, and to fieldworkers working in treated areas. Finally, in the risk characterization step, the exposure and dose-response assessments are generally combined to provide some quantitative estimate of the potential oncogenic risk to humans. This quantitative estimate is tempered, however, by the overall weight-of-the-evidence judgment on whether the chemical is likely to be a human oncogen. In cases where the qualitative evidence is not sufficient to support a quantitative oncogenic risk to humans, EPA must rely on its qualitative risk determination, including consideration of the uncertainties involved.

2. *Qualitative hazard assessment.* In this section, the results of long-term animal studies on dicofol are discussed, followed by a presentation and evaluation of the supporting data relating to the carcinogenicity of the compound. The section closes with an integrated discussion, leading to a weight-of-the-evidence conclusion on whether dicofol may be a human carcinogen.

a. *Long-term animal studies of dicofol.* In its January 1985 evaluation of the carcinogenicity of dicofol, DDT, DDE, and DDD, EPA reviewed the results of a 1978 NCI bioassay in which male B6C3F1 mice exposed to dicofol at two dose levels (264 ppm and 528 ppm in the diet) were reported to have non-metastasizing hepatocellular carcinomas at elevated levels in both dose levels when compared to controls. There were no other statistically significant increases in tumors reported in either sex of mice. A concurrent study did not show any statistically significant increase in tumors in either sex of Osborne-Mendel rats. EPA has concluded that the NCI mouse study is valid.

b. *Supporting data sources.* Other types of information which may be helpful in evaluating the carcinogenicity of dicofol are somewhat limited. There are no epidemiological studies which can be used to assess the direct response of humans to the chemical.

EPA's "Guidance Document for the Reregistration of Pesticide Products Containing Dicofol" indicated that EPA had no information on the mutagenicity of dicofol and directed that the full battery of tests be submitted by December 1986. EPA's review, therefore, did not include mutagenicity studies on dicofol, per se.

Dicofol is structurally similar to other DDT-related chemicals, for example, DDE, a carcinogenic metabolite of DDT. It is possible that dicofol may be metabolized or interconverted in animals to DDT metabolites, such as DDE (see Unit III.A.6). In order to assess fully the potential of dicofol to be metabolized or interconverted to oncogenic DDT metabolites, further study is required. Results from metabolism studies in rats, which were required as part of the reregistration process and are due in December 1986, and in avian species, which will be required through a Data Call-In notice, may shed additional light on this issue. Until additional studies are submitted and validated, the possible metabolic link between dicofol and DDT-related compounds remains tentative.

It is also possible that the mechanism of toxicity could be related to the physical structure of the compounds and not to a particular, common metabolite. EPA's report noted the structural similarity between dicofol, DDT, DDE and DDD. Based on this structural relationship, a determination that DDT is a "probable human carcinogen" (EPA's category B2), and the NCI test results for dicofol, EPA concluded that the weight-of-evidence also argued for a B2 classification for dicofol.

Subsequently, EPA received comments and supplementary information from a registrant, the Rohm and Haas Company, concerning the

carcinogenicity of dicofol, DDT, and DDE. These comments asserted that short-term and chronic data on dicofol do not indicate that the compound is carcinogenic. Specifically, Rohm and Haas argued that the observed mouse liver tumors are not adequate evidence for carcinogenicity and that the DOT carcinogenicity data should not be used to characterize the oncogenic potential of dicofol.

In order to resolve some of the issues raised about the dicofol long-term study, EPA requested a reevaluation of the pathology slides by scientific personnel at the National Toxicology Program. These results, together with the original readings, are shown in the following Table 1:

TABLE 1—DICOFOL MALE MOUSE LIVER TISSUE RESULTS

Tumor type	Control	Low	High
Hepatocellular carcinomas 1985 NTP Reviews	2/18 (11%)	12/48 (25%)	9/47 (19%)
1978 NCI Review	3/18 (17%)	22/50 (44%)	35/47 (74%)
Hepatocellular adenomas 1985 NTP Reviews	0/18 (0%)	13/48 (27%)	23/47 (49%)
1978 NCI Review	0/18 (0%)	1/50 (2%)	1/47 (2%)
Hepatocellular carcinomas or hepatocellular adenomas 1985 NTP Review	2/18 (11%)	25/48 (52%)	32/47 (68%)
1978 NCI Review	3/18 (17%)	23/50 (46%)	36/47 (77%)

While the vast majority of tumors in the original study were classified as carcinomas, the more recent slide evaluation reports a more significant proportion of benign tumors (adenomas). This difference may reflect changes which have evolved during the intervening years in conventions in the pathology community for classifying tumors. The combined incidence of benign and malignant tumors shows little change.

The EPA Proposed Guidelines for Carcinogenic Risk Assessment (49 FR 46294) state that "there are widely diverging scientific views" about the significance of certain mouse liver tumors for assessing risk to humans, and give specific guidance for the assessment of such tumors. The Guidelines take the position that the mouse-liver-only tumor response, when other conditions for a classification of "sufficient" evidence in animal studies are not met, should be considered as "sufficient" evidence of carcinogenicity with the understanding that this classification could be changed to "limited" if warranted when a number of factors such as the following are observed:

(1) The occurrence of tumors only in the highest dose group and/or only at the end of the study.

(2) No substantial dose-related increase in the proportion of tumors that are malignant.

(3) The occurrence of tumors that are predominately benign, showing no evidence of metastasis or invasion.

(4) No dose-related shortening of the time to the appearance of tumors.

(5) Negative or inconclusive results from a spectrum of short-term tests for mutagenic activity.

(6) The occurrence of excess tumors only in a single sex.

(7) Other data.

In the following paragraphs, each of these factors is discussed as it relates to the available information on dicofol.

(1) *The occurrence of tumors only in the highest dose group and/or only at the end of the study.* The data in Table 1 indicate that tumors were observed in both dicofol dose groups. Statistical analysis of the data in Table 1 shows that, for the combined tumors (adenomas and carcinomas), statistically significant increases were observed at both the low ($p=0.0035$) and the high dose ($p<0.001$). Therefore, on this basis, there is no reason to change the classification from "sufficient."

This criterion also speaks of the time in the study at which the tumors occurred. In the case of dicofol, the design of the experiment did not call for interim sacrifice; therefore, definitive evaluation of time-to-tumor-occurrence cannot be made. However, it can be noted that the mortality of the animals during the study was not remarkable. This at least suggests that the liver tumors were generally not life-shortening and possibly did not occur until the end of the study.

(2) *No substantial dose-related increase in the proportion of tumors that are malignant.* Examination of the 1985 NTP slide diagnoses (Table 1), reveals that there is no statistically significant dose-response relationship for the malignant tumors (carcinomas). Therefore, this would argue for reclassifying the dicofol data as "limited."

(3) *Then occurrence of tumors that are predominately benign, showing no evidence of metastasis or invasion.* The data in Table 1 for the 1985 NTP review indicate that the ratio of percentage adenomas to percentage carcinomas is 0, 1.0, and 2.6 for the control, low dose and high dose, respectively. This observation, which is consistent with the lack of a dose-related increase in malignant tumors noted in (2) above, supports a conclusion that benign tumors are the ones which are predominately related to the administered chemical. Further, the carcinomas in this case show no evidence of metastasis. Therefore, this information is supportive of a classification of "limited" for dicofol.

(4) *No dose-related shortening of the time to the appearance of tumors.* As indicated in (1) above, the design of the experiment was such that this information could not be obtained.

(5) *Negative or inconclusive results from a spectrum of short-term tests for mutagenic activity.* As noted above, EPA was unaware of data on the mutagenicity of dicofol and required the registrants to submit such data. However, in its response to the Special Review, Rohm and Haas indicated the existence of numerous studies. Reviews by their pathology panel led to the conclusion that dicofol is "clearly not a mutagen and appears to have little, if any, clastogenic potential." While EPA has not reviewed these data, on the basis of this information and a 1982 International Agency for Research on Cancer (IARC) evaluation of the mutagenicity of dicofol, there may be some support for reclassifying the dicofol data as "limited."

(6) *The occurrence of excess tumors only in a single sex.* This is the case for the dicofol mouse study. Therefore, this supports a "limited" classification for dicofol.

(7) *Other data.* The male mouse liver tumor incidence is not corroborated by a positive response in either sex of a comparably conducted Osborne-Mendel rat study. Therefore, this does not support the higher classification.

In addition, in the mouse study there was no other apparent response beyond that seen in the male mouse liver, a response whose relevance to humans has been questioned. This low response, without corroboration in other target organs, would tend toward reclassifying to "limited."

c. *Weight of the evidence classification.* Taken as a whole, this analysis supports the conclusion that

the evidence for the oncogenicity of dicofol should be reclassified as "limited" (as opposed to "sufficient") from studies in experimental animals. The only factor weighing in favor in maintaining the "sufficient" classification, the presence of tumors at two dose levels, is outweighed by the other factors.

In reaching a final hazard assessment position, consideration was also given to: (1) The plausible, but unverified, structure-activity relationship with the DDT series; (2) the possible connection between dicofol and the DDT related compounds via metabolism; and (3) the lack of human studies. Based on all of these considerations, EPA concludes that, at this time, there is limited qualitative evidence to support a conclusion that dicofol may be a human carcinogen. According to EPA's proposed Guidelines, dicofol would be classified in Group C: "This category is used for agents with limted evidence of carcinogenicity in animals in the absence of human data." EPA does recognize that there is some evidence which might suggest a different classification and has requested additional information through the Registration Standard and a subsequent Data Call-In notice to resolve the remaining issues.

3. *Dose-response assessment.* The second step in the risk assessment process calls for generation of a dose-response estimate. The EPA Proposed Guidelines discuss approaches to the mathematical extrapolation procedures used in this process. The Proposed Guidelines were followed by EPA in the generation of its January 1985 report.

However, as a result of the reassessment of dicofol discussed above which has transpired since the January report, EPA has concluded that the current dicofol data base provides limited evidence in support of the conclusion that dicofol is a potential human carcinogen. The confidence in the quantitative aspect of the risk estimate is limited by the nature of the qualitative hazard assessment on which it is based. Therefore, EPA has concluded that, in this instance, no quantitative risk assessment should be used for regulatory purposes for dicofol.

4. *Risk characterization.* The data base for dicofol consists primarily of two long-term animal studies (rat and mouse) in which the only statistically significant increase in tumors was observed in the male mouse liver. While the incidence of combined adenomas and carcinomas of this response was statistically significant at both the low and high dose, the malignant tumors did not appear in a dose-related manner, nor did they appear to be metastatic. The benign, rather than the malignant, tumors responded proportionately as the dose increased. Coupling these observations with a lack of corroborating evidence within the study (i.e., responses in other tissues and sex), from studies in another species, and from mutagenicity, metabolism and human studies, EPA finds that, at this time, no reliance can be placed on any quantitative risk estimates for dicofol.

Notwithstanding that there is only limited evidence at this time to support a conclusion that dicofol is a potential human carcinogen, it should not be overlooked that dicofol does cause tumors in the livers of male mice. While the significance of this response, particularly in light of the mitigating factors discussed above, is difficult to assess, it is of concern to EPA. The data clearly indicate that dicofol can interact in vivo to generate an oncogenic response, albeit one whose relevance to humans is also difficult to assess. Additional data are being collected through the Registration Standard and a subsequent Data Call-In notice which are expected to shed more light on the matter.

EPA's position on the potential oncogenic risks from dicofol is consistent with the conclusions of the Panel that the evidence that dicofol is a potential human carcinogen is weak and that a quantitative risk assessment is not justified.

C. Benefit Determinations

Available data indicate that approximately 60 percent of dicofol usage is on cotton and citrus, 10 percent on apples, and 10 percent on a combination of ornamentals and turf (commercial) plus home garden sites. The remaining 20 percent is used on a wide variety of sites including fruits, vegetables, and field crops. Dicofol, unlike most of the viable alternatives, is a selective miticide, not a broad spectrum pesticide (insecticide/miticide). Consequently, because it does not affect beneficial insects such as pollinators and most parasites and predators, its use is recommended in many integrated pest management (IPM) programs. In addition, dicofol is effective against more types of mite species than most other miticides and has both contact and residual activity. Further, dicofol has fewer phytotoxicity problems than other miticides.

EPA has evaluated the pesticidal properties of dicofol and, where data permitted, has compared its effectiveness to that of other pesticides registered for the control of mites on the same sites. In evaluating the suitability of using alternatives to dicofol, EPA considered a number of factors such as: The pre-harvest interval; the pre- or post-harvest restrictions; the number, timing, and frequency of permitted applications; reentry interval; required safety equipment or restricted applicator use; and the pests controlled on particular sites. Other important factors that were considered (compared) in determining whether a pesticide is an acceptable alternative to dicofol included: Production cost; comparative efficacy (degree of control and yield); compatability in mixtures with other pesticides; phytotoxicity; effect on nontarget organisms; impact on IPM programs; local resistance limitations; and variations of efficacy at different temperatures.

To assess alternatives to dicofol, each use site was evaluated separately because there may be an alternative to the use of dicofol on one crop in a group of related crops (e.g., citrus) but there may be no alternative to dicofol for other crops in the group (e.g., oranges versus kumquats). In other situations, alternatives are available but their use will involve an unknown economic cost because of localized resistance, lower efficacy, or the need to modify the applications. For a number of these sites, the available alternatives are currently being rotated with dicofol as needed or on a yearly or within season basis to slow the development of resistance among them.

EPA has estimated the economic impact of cancelling dicofol registrations on cotton, citrus, apples and other minor uses. These impacts are summarized below.

1. *Cotton.* The greatest portion of the economic impact resulting from the cancellation of all dicofol registrations would be felt by cotton producers in the San Joaquin Valley of California and to a lesser degree in Arizona. Unlike most other cotton-producing areas of the United States, the San Joaquin Valley frequently encounters severe, early-season spider mite infestations. Available information indicates that, unless dicofol is used, these infestations cannot be controlled effectively without either imposing significant financial loss on growers and/or increasing the development of pest resistance to propargite, the only selective miticide alternative to dicofol. This would occur because all of the selective pressure for resistance would be from the continuous use of propargite. Propargite is phytotoxic to young cotton plants; therefore, it is estimated that growers would lose 3 to 5 percent in yield because it cannot be used early enough

in the season. Another registered material, sulfur, is ineffective under climatic conditions existing early in the growing season for cotton in the San Joaquin Valley. The unavailability of dicofol for early-season infestations would result in yield losses and increased control costs, which taken together, would increase the average variable cost of production (per pound of seed cotton) by 5 to 7 percent. For all San Joaquin Valley cotton producers who are current users of dicofol, the total impact would range from $11.2 to $17.7 million annually.

Cancellation of the use of dicofol on cotton would have considerably smaller impacts in areas outside the San Joaquin Valley. In Arizona, cotton producers now using dicofol could switch to propargite at an additional cost estimated to be approximately $3.62 per acre-treatement, or approximately $200,000 in the aggregate (a 1 percent increase in variable production costs). Use of other broad spectrum pesticides at no incremental costs is also possible where IPM systems are not currently established. In the Southeast United States and the Mississippi Delta, dicofol users could switch to monocrotophos or other possible alternatives at no incremental costs, unless they have a pest management program that would require propargite or sulfur as an alternative.

2. *Citrus (grapefruit, lemons, oranges).* The economic impacts of cancelling the use of dicofol on citrus (primarily grapefruit, lemons, and oranges) are estimated to be between $3.1 and $10.4 million annually due to the higher cost of using alternatives. This is a 1 to 2 percent increase in the variable costs of production. Based on current information, EPA does not expect significant impacts on yield or quality when alternatives are used. The available alternatives vary by region due to labeling limitations, differences in mite species, mite resistance, and climatic conditions. The alternatives include chlorobenzilate plus oil, oxythioquinox, propargite, cyhexatin, fenbutatin-oxide, and ethion plus oil.

3. *Apples.* EPA estimates that apple growers, primarily in the Northeast and Northcentral regions, would incur annual, incremental treatment costs ranging from $4.1 to $6.4 million. This is a 2 to 3 percent increase in the variable costs of production (e.g., more costly alternatives). This estimate reflects a substantial increase in EPA's estimate of dicofol usage in comparison with that made in the PD 2/3 and is based on more complete data submitted in public comments and collated by EPA since the PD 2/3. Dicofol fits into established IPM programs on apples, which are aimed primarily at spider mite control. Moreover, the dicofol usage on apples is increasing concurrently with reports of mite resistance to alternatives.

As in the case for citrus, the alternatives identified are currently used in rotation with dicofol; therefore, it is anticipated that their increased usage would further hasten development of mite resistance to them.

4. *Other minor uses.* EPA has concluded that there are no suitable alternative pesticides or nonchemical controls to replace dicofol registered on the following sites and site groupings: Some ornamentals and turf (commerical), home gardens (some ornamentals, a number of food crops), cucurbits (cucumbers, melons, pumpkin and squash), peppers, Bermudagrass (seed crop), cyclamen mite on strawberries, areas east of the Rockies for dry beans, and spider mites on tomatoes.

The use sites for which alternatives have been identified and costs estimated include: Stone fruits (apricots, cherries, peaches/nectarines, plums/prunes); caneberries (blackberries, dewberries and raspberries); figs; alfalfa (seed crop); sugarbeets (seed crop); red clover (seed crop); pears; peanuts; grapes; pecans; mints (peppermint and spearmint); hops; eggplant; strawberries; tomatoes; dry beans west of the Rockies; and field corn (California only). In general, pest scouting and monitoring are an important IPM component utilized in pest control on these and the principal sites discussed earlier.

Although the additional costs involved are low, on dry beans (California), field corn (California), melons, cherries, alfalfa (seed crop), Bermudagrass (seed crop), and mints and hops, the percentage of acreage treated with dicofol represents a significant portion of the acrage grown. The same appears to be true of ornamentals and turf (commerical) and the homegarden sites, but precise, reliable data are lacking.

The total cost of cancelling dicofol for all minor sites is estimated as approximately $2.2 to $4.3 million.

5. *Mite resistance to pesticides.* EPA recognizes that for some uses of dicofol there are benefits which are not readily demonstrable or quantifiable in monetary terms but which, nonetheless, may be important. One of these benefits relates to the impact of dicofol's cancellation on mite resistance. It is well established that intensive use of a pesticide creates selective pressures that may lead to pest populations resistant to that pesticide. This is more likely to be true of mite and insect species that produce many generations annually. Data show that mite species in some areas and crops are resistant to various registered miticides, including dicofol. The number of selective miticides is limited, and if that number is reduced, pest resistance may intensify or appear more rapidly than it would otherwise. This is the case with dicofol, which is the last chlorinated hydrocarbon miticide. EPA expects this phenomenon to be more significant in crops where mite infestations recur annually (e.g., some cotton, citrus, and apple acreage) than in crops where the level of mite infestations (i.e., economic vs. noneconomic) fluctuate widely from year to year. Where alternatives are available, the most common method of reducing the development of resistance appears to be rotating mite pesticides. This frequently is combined with monitoring mite populations and timing pesticide applications to reduce the number of treatments per season.

6. *Summary.* The immediate quantifiable impacts from cancellation of dicofol products would range from about $21 to $39 million per year, with the bulk of such impacts (approximately 90 percent of the total) accruing to producers of cotton in the San Joaquin Valley, citrus (mainly in Florida), and apples (mainly in the Northeast and Northcentral States) who are among the major current users of dicofol. Established IPM programs are a part of the overall determinations for pest management particularly for apples and San Joaquin Valley cotton. Given the competitive nature of agriculture and that in most cases only a small percentage of the crops would be affected, it is unlikely that the affected growers would be in a position to pass these incremental costs on to consumers since their commodities would be unable to compete with lower priced commodities sold by unaffected producers.

It must be recognized, however, that the range of $21 to $39 million represents a partial estimate of the total impact from cancellation. EPA was unable to quantify monetary benefits from dicofol use on a number of sites. In view of the usage on these sites, and given the lack of selective miticide alternatives for some crops, the impact from cancellation is likely to be significant for the affected producers of those crops. Therefore, should all of the potential developments actually come to pass (e.g., resistance, phytotoxicity from alternatives, etc.), the total impact from

cancellation would exceed the $21 to $39 million range.

IV. Initiation of Regulatory Actions

A. Introduction

This unit has several sections. The first, this Introduction, discusses EPA's reasons for concluding that dicofol products, as currently registered, should be cancelled unless certain modifications are made in the terms and conditions of registration. This Introduction also contains definitions of a number of terms used in the rest of this unit. The second section of this unit specifies the modifications in the terms and conditions of registration for federally registered pesticide products that are required for the products to remain registered. Section C explains how these requirements apply to intrastate pesticide products. Section D completes this unit and establishes provisions concerning the sale, distribution, and use of existing stocks.

1. *Statutory determinations.* Based upon the determinations summarized in Unit III, EPA has concluded that the use of currently registered pesticide products containing dicofol causes unreasonable adverse effects on the environment. A number of factors lead EPA to conclude that the risks of using dicofol outweigh its benefits, and, therefore, that cancellation is appropriate unless modifications are made to the product registrations. Most important is the evidence that dicofol contaminated with an average of 10 percent DDTr causes significant adverse effects on the environment by harming both fish and avian species, including endangered species. EPA realizes that some dicofol products now have no more than 2.5 percent DDTr in the active ingredient. EPA believes that these products also make a significant contribution of DDTr to the environment, and that the environmental risks, while somewhat lower, are qualitatively comparable to the risk from using more highly contaminated dicofol. Both the OES and the Panel agreed with EPA that it should cancel the registration of dicofol products because of the magnitude of these environmental risks. In addition to the risks to the environment, dicofol may pose a carcinogenic risk to humans. Although the evidence of carcinogenicity is weak, this risk cannot be ignored.

The fact that the estimated benefits of using dicofol, while approaching $40 million a year, are confined to certain geographical areas and crops, was also an important factor in EPA's decision. EPA recognizes that cancellation would have sizeable impacts on cotton growers in California and citrus growers in Florida, and to a lesser extent on apple growers in some Northern States, but these impacts should not significantly affect consumer prices or the national supply of these commodities. Dicofol applied to cotton and citrus accounts for the largest proportion of its use; the other sites to which dicofol is applied are generally considered minor uses. Thus, the impact of cancellation of uses, other than possibly cotton, would not be significant for the national agricultural economy, although some local impacts could be severe.

EPA has also concluded that dicofol products can meet the statutory standard for continued registration under FIFRA if certain modifications of the terms and conditions of registration are made by the registrants. (EPA's conclusion that the benefits of using dicofol would outweigh risks if certain changes are made, takes into account that the adverse effects on the peregrine falcons resulting from continued use of dicofol in California will be significantly mitigated by the nest manipulation project partly funded by the major producers of dicofol.) EPA has concluded that two kinds of modifications are necessary. First, registrants must reduce the level of DDTr contamination in dicofol products. EPA believes the registrants' proposed reductions, initially to less than 2.5 percent DDTr and within 2 years to 0.1 percent DDTr or less, should substantially reduce the environmental risks of using dicofol. EPA desires that the production, sale, and use of dicofol with these lower levels of DDTr contamination begin as quickly as feasible. Accordingly, EPA has established a schedule by which registrants must produce dicofol products with specified limits for DDTr contamination.

The second condition under which EPA will permit continued registration of dicofol products is the addition to the product label of a requirement that mixers, loaders, and applicators are to wear gloves while handling dicofol. The reasons for these two conditions are discussed below.

The registrants' proposed reduction in the level of DDTr contaminants in their technical products would significantly lower the amount of DDTr released into the environment as the result of using dicofol. Assuming that use of dicofol products does not increase significantly in the future, use of products contaminated with DDTr at 0.1 percent or less, the level which registrants indicate they can begin producing by late 1987, would result in the introduction into the environment of approximately 20 to 50 times less DDTr than results from use of currently registered dicofol products. At this proposed level of DDTr contamination, using the mass balance analytical techniques described by EPA in PD 2/3, by the year 2000, the new contribution of DDTr to the environment from the new product would be 1 percent of that attributable to use of DDT prior to its cancellation in 1972 and the old, more highly contaminated dicofol products. While this incremental contribution would not be free from risks, it would represent a substantial reduction in the level of risk to the environment. EPA agrees with OES that the expeditious phase-out of dicofol products containing more than 0.1 percent DDTr would be adequate to prevent jeopardy to the endangered peregrine falcon in California in view of other efforts being made to support recovery of this species. The reduction in DDTr contamination level should not noticeably alter either the price or effectiveness of dicofol products. Thus, the required reduction in DDTr will not affect the benefits of dicofol.

This notice establishes a schedule for reducing the level of DDTr contamination in dicofol products. Because the major producers of technical dicofol have informed EPA that they are already capable of or are making the active ingredient with less than 2.5 percent DDTr contaminants, EPA is requiring an immediate amendment to dicofol registrations to certify an upper limit on DDTr contaminants equivalent to 2.5 percent (or less) of the technical grade material. Registrants have indicated that production of dicofol with 0.1 percent or less DDTr requires construction of new manufacturing facilities, and that the facilities would not be operational until late fall of 1987. Moreover, the initial production from the new facilities may be inadequate to meet demand for dicofol products during the 1988 growing season. Accordingly, EPA is allowing registrants to sell and distribute stocks of dicofol containing between 2.5 percent and 0.1 percent DDTr until December 31, 1988. These additional quantities of dicofol products should help meet the demand for use of dicofol products. At the same time, these unavoidable additions to the existing environmental residues of DDTr will be relatively limited.

This schedule is consistent with the timeframes recommended by OES in its March 1986 Biological Opinion on dicofol. After concluding that the

continued use of dicofol would jeopardize the continued existence of the endangered peregrine falcon. OES listed, as part of one reasonable and prudent alternative, the phase-out of dicofol products contaminated with more than 0.1 percent DDTr. OES indicated that in California the sale of dicofol products containing more than 0.1 percent DDTr should stop by December 31, 1988.

In addition, although EPA has concluded that the evidence that dicofol is a potential human carcinogen is weak, EPA finds it prudent to require the use of chemical resistant gloves while handling products containing dicofol. The chances for human contact with the pesticide are greatest during the mixing, loading and application processes, and use of chemical resistant gloves should diminish skin contact with dicofol and reduce whatever risks to humans may result from such exposure. Such a requirement would have virtually no impact on the benefits of using dicofol.

In summation, based on available information, EPA finds that the risks posed by the use of dicofol would be outweighed by the benefits if certain modifications are made to the registration of dicofol products. Accordingly, EPA is issuing a "conditional" cancellation notice. In other words, registrations will be allowed to continue provided that the registrants amend their registrations to make the required modifications as described in Unit IV.B below.

EPA notes that its evaluation of the risks and benefits of using dicofol is based on available data and that if EPA receives additional information which changes its conclusions concerning risks or benefits, it might initiate different regulatory actions. EPA is particularly concerned that dicofol, independent of the effect of its DDTr contaminants, may pose a risk to the environment. If this concern is confirmed or if new data strengthen the evidence of the carcinogenicity of dicofol, EPA will consider further regulatory action.

2. *Definitions.* The following terms are defined for the purposes of this unit.

a. The term "existing stocks" refers to any quantity of dicofol products which is in the United States on the date of the publication of this notice and which is formulated as either an end-use product or manufacturing-use product.

b. The term "basic manufacturer" refers to any registrant who sells or distributes a manufacturing-use product containing technical dicofol or an end-use product containing technical dicofol produced from an unpurchased and/or unregistered source (integrated formulation system).

c. The term "formulator" refers to any registrant (or supplemental distributor registrant) who is not a basic manufacturer and who sells or distributes an end-use product containing dicofol.

d. The term "sale or distribution" and grammatical variants such as "sell or distribute" refer to the distribution, sale, offering for sale, holding for sale, shipping, delivering for shipment, or receiving and (having so received) delivering or offering to deliver a pesticide product.

e. The term "released for sale or distribution" refers to any quantity of a pesticide product that has left the physical custody of the registrant.

f. The term "products containing more than 2.5 percent DDTr" refers to manufacturing-use products and/or end-use products that contain DDTr contaminants at a level greater than 2.5 percent of the amount of technical grade dicofol in the product.

g. The term "products containing between 2.5 percent and 0.1 percent DDTr" refers to the manufacturing-use products and/or end-use products that contain DDTr contaminants at any level equal to or less than 2.5 percent and more than 0.1 percent of the amount of technical grade dicofol in the product.

h. The term "products containing less than 0.1 percent DDTr" refers to manufacturing-use and/or end-use products that contain DDTr contaminants at any level equal to or less than 0.1 percent of the amount of technical grade dicofol in the product.

B. Requirements for Complying with This Notice—Federally Registered Products

The registrant of a product containing dicofol must submit an application for amended registration, as specified below, within 30 days of publication in the **Federal Register** or receipt by the registrant of this notice, whichever is later, in order to be allowed to continue to sell and distribute the product. Refer to Unit VI.A of this notice for directions on how to submit an application for amended registration. This unit sets out substantive requirements for the application for amended registration.

1. *New Confidential Statement of Formula.* Registrants of dicofol products must apply to amend their registrations to reflect the composition of their products on a new Confidential Statement of Formula. For each manufacturing-use product and each end-use product, the registrant must also establish an upper certified limit for DDTr equal to or less than 2.5 percent of the amount of technical grade dicofol in the product. The Confidential Statement of Formula must be accompanied by information showing that the registrant can produce his product with no more DDTr than the amount certified as the upper limit.

If the application is otherwise acceptable, the amendment will be approved conditionally. The amended registration will be conditioned on submission and approval before March 30, 1988, of an application for amended registration which revises the composition of the product to establish a new upper certified limit for DDTr equal to or less than 0.1 percent of the amount of technical grade dicofol in the product. As before, the application must be accompanied by information showing that the registrant can produce his product with no more DDTr than the amount certified as the upper limit.

The registrants have indicated their intention to reduce the level of DDTr contamination to 0.1 percent according to the schedule specified in this notice. EPA intends to monitor the registrants' progress closely to assure that this schedule is met and, if circumstances warrant, to take appropriate regulatory action under FIFRA.

2. *Revised labeling.* Registrants of dicofol products who apply for amended registration to certify an upper limit for DDTr between 2.5 percent and 0.1 percent of the technical dicofol must also apply to revise their labeling to including the following statements.

a. On the top of the front panel add the statement: Not to be sold, offered for sale, held for sale, shipped, delivered for shipment, offered for delivery, or received after December 31, 1988. Not to be used after March 31, 1989. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, of the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

b. In the beginning of the directions for use add: Skin contact with this pesticide may be hazardous; wear chemical resistant gloves when mixing, loading, or applying this product.

Registrants of dicofol products who apply for amended registration of their products to certify an upper limit for DDTr equal to or less than 0.1 percent of the technical dicofol in the product must delete the statement in item a above.

The registrations of all dicofol products containing greater than 0.1 percent DDTr are cancelled on December 31, 1988. Selling, offering for sale, holding for sale, shipping, delivering for shipment, offering for delivery, or receiving of these products

after December 31, 1988 is a violation of this cancellation order.

C. Requirements for Complying with this Notice—Intrastate Products

The producer of an intrastate product is required to submit an acceptable application for Federal registration, or acceptably amend a pending application, within 30 days of receipt by the producer of this notice. (An intrastate product is a pesticide product that was initially registered by a State prior to 1972, that is distributed and sold solely within a single State, and that is in compliance with the requirements of 40 CFR 162.17.) To be acceptable, the application must comply with all of the requirements imposed on Federal registrations by Unit IV.B of this notice. Other requirements for an acceptable application are described in the Registration Standard for dicofol and pertinent EPA regulations in 40 CFR Part 162. Refer to Unit VI.B for directions on how to apply for Federal registration of an intrastate product.

D. Existing Stocks

The following paragraphs describe the conditions under which registrants and others may sell, distribute, and use existing stocks of dicofol products. The conditions depend on the level of DDTr contamination, the kind of product, and whether the registrant has released the products for sale or distribution. Existing stocks may not be sold, distributed, or used except as provided below.

1. *Existing stocks of dicofol already released by the registrant.* Any person, other than a basic manufacturer or formulator, may sell or distribute, or use in accordance with label instructions, any quantity of existing stocks of end-use products containing more than 0.1 percent DDTr until depletion, provided that such products were released for sale or distribution by the registrant before the date of publication of this notice.

2. *Existing stocks of products containing more than 2.5 percent DDTr not released for sale or distribution by the date of publication of this notice.* Any registrant may sell or distribute any quantity of existing stocks of dicofol products containing more than 2.5 percent DDTr provided that such stocks were released for sale or distribution by the registrant before June 30, 1986. Stocks released for sale or distribution after June 30, 1986 may be sold or distributed provided that the labeling includes the following statements:

On top of the front panel:

Not to be sold, offered for sale, held for sale, shipped, offered for delivery, delivered for shipment, or received and (having so received) delivered or offered for delivery after October 31, 1988.

Not to be used after June 30, 1987.

Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

In the direction for use section:

Skin contact with this pesticide may be hazardous; wear chemical resistant gloves when mixing, loading or applying this product.

The statement required on the front panel may be added by applying a sticker to the product container. The statements required in the use directions may be added in the form of supplemental labeling accompanying the product.

3. *Existing stocks of manufacturing-use and end-use products containing between 2.5 percent and 0.1 percent DDTr not released for sale or distribution by the date of publication of this notice.* Any registrant may sell or distribute any quantity of existing stocks of manufacturing-use or end-use products containing dicofol with between 2.5 percent and 0.1 percent DDTr provided that such stocks were released for sale or distribution by the registrant before August 27, 1986. Stocks released for sale or distribution after August 27, 1986 may be sold or distributed provided that two conditions are met: (1) Within 30 days of publication or receipt by the registrant of this notice, the registrant must submit a completed application for amended registration and submit five copies of draft labeling, amended to include the following statements:

On the top of the front panel add:

Not to be sold, offered for sale, held for sale, shipped, delivered for shipment, offered for delivery, or received after December 31, 1988. Not for use after March 31, 1989.

Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

In the beginning of the directions for use add:

Skin contact with this pesticide may be hazardous; wear chemical resistant gloves when mixing, loading or applying this product.

and (2) such existing stocks of dicofol products must bear the amended labeling when released for sale or distribution.

V. Comments of the Secretary of the United States Department of Agriculture, the Scientific Advisory Panel, and Other Public Comments

A. USDA's Response to the October 10, 1984 Federal Register Notice

The United States Department of Agriculture (USDA) responded to the October 10, 1984 **Federal Register** notice as well as the Position Document 2/3. Their comments are printed in full below:

Honorable Steven Schatzow,
Administrator [sic], U.S. Environmental Protection Agency, Washington, D.C. 20460

Dear Mr. Schatzow: This is the United States Department of Agriculture's (USDA) response to the U.S. Environmental Protection Agency's (EPA) Preliminary Notice of Determination Concluding the Special Review of Pesticide Products Containing Dicofol.

State extension and research personnel responsible for pest control technology and recommendations were contacted by USDA concerning the agricultural needs for dicofol. These experts expressed the view that dicofol is an effective miticide, is economical, has been extensively used for many years and has not been a serious object of mite resistance. The USDA concurs with their assessment and believes that the following comments should be considered by the ageny in developing the final regulatory decisions.

1. EPA proposes a standard for cancellation with differs from that in FIFRA. FIFRA sec. 6 provides for notice of intent to cancel a registration "[i]f it appears to the Administrator that a pesticide . . . generally causes unreasonable adverse effects on the environment. . . ." PD 2/3 changes the meaning require only that "the pesticide appears to cause unreasonable adverse effects on the environment."

2. EPA fails to explain exactly how the risks of using dicofol were weighed against its benefits, which are acknowleged. In several places the document concludes arbitrarily that "these risks outweigh the benefits," or similar language. However, nowhere is any objective methodology for weighing risks against benefits explained. In the absence of such methodology, which could be used by any neutral observer to reach an independent conclusion when supplied with the facts, we can only judge that EPA's conclusion is predetermined. That is, EPA appears to conclude that any risk is unacceptable, no matter what the benefits of continued use might be. Also, the concept of weighing risks of reduced levels of DDTr in dicofol does not have a chance of objective evaluation because there is no definition of what those levels might be.

3. USDA believes that EPA, when studying the idealized model representing

environmental loads resulting from applications with dicofol, has not given sufficient consideration to undefined or unidentified sources of DDTr. Nor has EPA adequately considered variable and transitory loads contributed by background environmental residues. EPA points out in the document that background levels are transitory. USDA believes however, that evaluation of residues in wildlife specimens as representative of dicofol use loads may well be in error. This would be especially true for the analysis of migratory wildlife that could easily range into other geographic areas, perhaps including those where DDTr occurrence is acceptable, for example, Mexico.

4. Much of the evidence cited in the text of EPA's PD 2/3 is the result of earlier wildlife studies dealing directly with DDT as well as DDTr. Some of the evidence is the result of direct feeding studies which although relevant in the broader sense may not accurately describe the present situation. Additionally, the narrative of the PD 2/3 often refers to both DDT and the DDT homologs in a manner that suggests that all are implicated in this special review. However, EPA identifies the eight DDT homologs as the subject of regulatory concern. A valid question might be whether DDT-induced biological responses would accurately typify the same metabolic reactions with the same magnitude as those induced by DDT homologs. It would be interesting as well to determine whether U.S. Fish and Wildlife scientists who have monitored wildlife residues concur with EPA's assessment of dicofol as an indisputable source of the DDTr residues that have been identified in wildlife.

5. In the draft PD 2/3, EPA discusses possible oncogenicity resulting from exposure to dicofol formulations and states that evidence in support of that allegation may be presented in the forthcoming PD 4 final decision, if corroborating information can be obtained. USDA views this action as an unusual means of attaining a rational and judgmental conclusion insofar as the PD 4 is expected to present a regulatory decision, and would not allow adequate opportunity for comment.

6. The Department and State scientists question that there are satisfactory alternatives for nearly all uses of dicofol. The USDA report of "Dicofol Use and Efficacy in Agriculture" shows that of 47 individual commodities or groups of commodities, only six were inconclusive about adverse effects that result from the loss of dicofol through regulatory action. These commodities were hops, mint, peas, onions, sugarbeets, and red clover seed. A seventh commodity group, ornamentals, reflected some lack of concern about the possible loss of dicofol, but that concern varied widely and inconsistently across geographical areas and plant varieties. The more important and major agricultural crops were presented as having significant dependence on dicofol.

7. Although EPA has assumed that regulatory removal of dicofol will have no adverse effect upon minor crops, USDA data indicated that the control of mites on certain crops would be difficult or impossible without dicofol. These were stated to be artichokes in California, Easter lily bulbs in Montana, figs in South Carolina, grapes in Michigan and California, ornamentals in Maine and New Jersey, beans in several states, homeowner uses in several states (house plants), lawns in Alabama, pecans in South Carolina, peppers in California, home grown plums in Illinois, and vegetables in several states. These examples do not include many instances where state specialists indicated that while registered alternatives might exist, they are not suitable due to various biological and/or economic reasons.

8. EPA expressed the view that overall, the removal of dicofol from the market and substitution with alternative miticides would result in no yield loss. USDA understands that the comments are intended to convey the idea that the same weight or volume of crop production would be achieved. Assuming this to be true in certain instances, USDA feels that yield is a single parameter in agricultural production that is meaningful only in the instance that time, energy, and costs of materials and equipment remain constant. USDA has shown in its report, that without dicofol one or more of those factors will necessarily increase. Thus, obtaining identical or similar yields with alternative miticides could have undesirable pest control and production consequences. In addition, State specialists have reported that some crops would be impossible to grow in certain production regions without the continued availability of dicofol.

9. EPA has described a potential initial economic impact of between 9.6 to 31.9 million dollars to cotton growers with the removal of dicofol, and projected a greater long term impact of 11.0 to 37.1 million dollars. The draft PD 2/3 indicates that this will primarily result in economic hardship to cotton growers in the San Joaquin Valley of California, many of whom would elect to grow less profitable crops. It was stated that the current national base acreage (in excess of 15 million acres) would enable U.S. cotton growers to fill the supply gap. USDA does not agree with this economic appraisal because of the following reasons.

(a) Even a 20 percent production loss as stated by EPA would be difficult to rationalize on grounds of production efficiency when it is considered that few geographic areas can compete on a per acreage production cost basis with the San Joaquin Valley. In the Valley, per acre yields of cotton are substantially higher than in any other State, except Arizona.

(b) EPA's Benefit Summary of PD 2/3 projected a reduction in budgetary outlay by the Federal Government to the San Joaquin Valley growers based on a 4.4 to 7.3 million dollar projected cotton production loss. However, this loss value is certainly too low. If cotton production were to be sharply reduced, USDA believes that an attempt also should be made to add in the costs to the growers and to the local agricultural community that would be incurred through the necessary disposal of machinery, equipment, and facilities now used for cotton, and the acquisition of other equipment needed for the production of replacement crops.

(c) The unique agricultural environment of arid California is such that growers of less profitable crops than cotton will themselves be subject to additional economic stress. Obviously additional acreages of the San Joaquin Valley competing in their specific crop market could result in severe economic consequences due to price competition and the availability of adequate markets. Secondly, as the USDA assessment report has shown, there will be serious economic impacts on other crops due to increased production costs in the event that dicofol uses are cancelled.

10. EPA indicates that economic impacts to citrus growers are expected to initially range from 3.5 to 4.0 million dollars. Additionally, it is stated that 73 percent of dicofol use on citrus is applied in Florida. EPA concluded that the resultant increases in production costs in Florida would not be excessive and that it would be expected that those costs would be passed on to the public. USDA is concerned that the Florida citrus industry has been affected very badly in recent years, first by successive killing frosts that have destroyed major portions of the producing groves as far north as the St. John River citrus region and southward to the middle of the state. There is also a current crisis among some of the larger citrus nurseries in Florida resulting from the citrus canker. Taken together, the present prospect for the Florida citrus industry is one of risk and hardship. Alternative miticides might introduce biological problems as well as economic hardship as described in the USDA assessment report. It is extremely important for Florida citrus growers to be able to avail themselves of all available tools during the lengthy rebuilding, nonproductive years required for new orchard establishment.

USDA believes that the information and the data provided by State and Federal scientists has established the critical need to retain dicofol uses for the agricultural community. We further believe that sufficiently low levels of DDTr in the product can be achieved and EPA is encouraged to work closely with the basic producers toward this end.

We are forwarding with this letter an updated copy of our report and copies of the information we received from the field. We are also providing copies of this material to the Rohm and Haas Company at their request.

USDA believes that the need and use of dicofol is important in pest control technology and recommends its continued registration. The Department appreciates the opportunity to have cooperated in this important agricultural decision.

Sincerely,

Charles L. Smith,

Coordinator, Pesticides and Pesticide Assessment.

Dated: December 11, 1984.

B. USDA's Response to the August 15, 1985 Federal Register Notice

The USDA responded to the August 15, 1985 amended **Federal Register**

notice. Their comments are printed in full below.

Mr. Steven Schatzow,
Director, Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, DC 20460.

Dear Mr. Schatzow: This is in response to your letter of August 12 forwarding a revised PD 2/3 for the pesticide chemical dicofol. EPA is to be commended for its rational approach in this document.

We also appreciate your acceptance of many of the comments we gave you in December 1984. We anticipate that those comments will be published in the next Federal Register notice.

Sincerely,

Charles L. Smith,
Coordinator, Pesticide and Pesticide Assessment.

Dated: September 13, 1985.

C. EPA's Response to the Comments of the Secretary of the United States Department of Agriculture

EPA appreciates the cooperation of the USDA in providing comments on the proposed regulatory decision concerning dicofol. Following is a point-by-point response to USDA's December 11, 1984 comments. No response to the September 13, 1985 comments is considered necessary.

1. EPA believes that the standard applied in deciding whether to propose cancellation of the registrations of dicofol products, both in the PD 2/3 and in this final Notice of Intent to Cancel, is the standard prescribed by FIFRA sec. 6. FIFRA sec. 6(b) provides that, "If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this Act or when used in accordance with widespread and generally recognized practice, generally causes unreasonable adverse effects on the environment, . . ." the Administrator may issue a Notice of Intent to Cancel the registrations of the pesticide. Because of the definition of the term "unreasonable adverse effects," this standard directs EPA to balance the risks against the benefits of using a pesticide and, if risks generally outweigh the benefits, EPA may propose cancellation. As explained in Units II and IV, this is the analysis used by EPA.

2. EPA is unaware of any objective methodology for weighing risks against benefits that adequately takes into account all relevant factors. Therefore, EPA necessarily makes a policy judgment. Such decisions, however, are hardly arbitrary and predetermined, as evidenced by the regulatory changes that often take place from the PD 2/3 to the PD 4 stage of a Special Review. EPA disagrees with USDA's assertion that the weighing of risks of reduced levels of DDTr in dicofol does not have a chance of objective evaluation because there is no definition of what those levels might be. The levels of DDTr were estimated, the corresponding effect on exposure was evaluated, and a determination was made on whether the risks to the environment posed by such effects outweighed the benefits of use. Unit IV of this notice contains a more extensive discussion of EPA's analysis than appeared in PD 2/3.

3. The model used to predict residues of DDTr in the environment resulting from use of dicofol incorporated realistic assumptions into its calculations. The model assumed a zero background level of DDTr. To the extent that there would be background levels, they would only increase the exposure and hence the risk to wildlife. While it is true that migratory wildlife could be exposed to DDTr in other geographic areas where the use of DDT may be legal, EPA's models and calculations do not include such routes of exposure. Thus, the models did not intentionally overestimate exposure to DDTr from dicofol use as USDA implies.

4. Although USDA states that the use of laboratory studies to evaluate the effects of DDT on avian reproduction "may not accurately describe the present situation," USDA gives no reasons for this conclusion. EPA believes that laboratory studies of the toxicity of DDT to wild birds represent the best way of evaluating what levels of DDT will cause adverse effects on avian species. In evaluating the risks of DDTr, EPA examined the results of studies using both DDT and DDE, including the p,p' and o,p' isomers of each chemical. The data base on these four substances was extrapolated to the other components of DDTr, because the homologs have not been studied extensively and because these homologs may convert to DDE. Finally, EPA has never asserted that dicofol is an indisputable or sole source of DDTr residues found in wildlife.

5. USDA's concern that it may not have adequate opportunity to comment on the possible oncogenicity of dicofol before EPA issues its PD 4 final decision is now moot. EPA asked for comment from USDA on the revised PD 2/3 which extensively discussed the oncogenicity of dicofol. USDA had no comment.

6. The issue of availability of economically feasible alternatives has been addressed at length in the revised benefit analysis in Unit III.C of this notice. Specifically, the analysis points out that with the cancellation of dicofol there would be no selective alternative miticide available for use on cucurbits, Bermudagrass (as a seed crop), peppers, dry beans east of the Rockies, spider mite control on tomatoes, a number of ornamentals, and many homeowner crop and ornamental sites. A number of other sites have only a single selective miticide alternative. In general, there is no question that benefits are derived from the use of dicofol in the production of a number of crops. Indeed, the objective of the benefits analysis was to measure the magnitude of such benefits. In the revised benefits analysis, the aggregate impact of cancellation of the uses of dicofol was estimated, at a minimum, to range from roughly $20 to $40 million per year (measured as increased production costs to agricultural producers).

7. As stated above, the revised benefits analysis addresses the impacts of cancelling dicofol use on minor crops. While it is true that for minor sites there would not be a large economic impact when compared to agricultural income as a whole, EPA nevertheless recognizes that there will be significant impacts on some individuals and growers. It should be noted, however, that dicofol is not registered for artichokes as stated by USDA.

8. For those crops which EPA evaluated for alternative miticides, none appeared to have significant yield losses, with the exception of cotton in the San Joaquin Valley. In the latter case, in most years, alternatives would have to be applied too late in the season to prevent a percentage of the early-season spider mite damage. EPA did not evaluate other crop and ornamental sites in enough detail to quantify the impact of cancelling the use of dicofol. EPA recognizes, however, that the lack of dicofol would cause significant losses on certain crops and ornamentals, nationally or in areas where resistance or other local factors limit or restrict alternatives. On a number of sites where integrated pest management practices are used, few if any selective alternative miticides are available.

9. USDA disagrees with EPA's evaluation of the impacts of dicofol on cotton growers in California. This disagreement is based in part on a misunderstanding of EPA's benefits analysis. Contrary to USDA's comment, at no time did EPA project a 20 percent loss in production in the San Joaquin Valley as a result of cancelling dicofol. It must be kept in mind that the objective of a benefits analysis is to measure the economic impact resulting from the cancellation of a pesticide not only on production, but also on the agricultural economy in general.

consumers, and the overall society. The estimation of such impacts does not suggest that the end result will be optimal from the cotton producer's perspective. Given accurate information on both the risks and benefits of dicofol, one can hopefully make a risk/benefit decision which is optimal from society's viewpoint.

The revised cotton analysis concluded that few if any producers would be forced out of cotton production in the San Joaquin Valley. This revised estimate reflects the use of more detailed estimates of cotton production costs which show that, given expected cotton yields and prices (based on long term averages), San Joaquin Valley growers would sustain reduced profits, but would not be forced out of the cotton business.

10. USDA's concerns over the impact of dicofol's cancellation on citrus are valid and the benefits analysis has been revised accordingly.

D. Comments of the Scientific Advisory Panel

EPA transmitted the PD 2/3 to the Scientific Advisory Panel (Panel) for review. At that time, the Panel was asked to comment on the environmental concerns. On April 17, 1985 the Panel responded to EPA. EPA then sent to the Panel an amended notice in draft form concerning EPA's concerns with the oncogenicity of dicofol. On July 8, 1985, they responded to EPA. Because FIFRA requires that the Panel's comments be printed, comments from both meetings are reproduced in their entirety.

1. *Comments following the April 1985 meeting:* Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Scientific Advisory Panel.

Review of a Set of Scientific Issues Being Considered by EPA in Connection with the Special Review on Dicofol.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed review of a number of scientific issues associated with the Special Review of the pesticide dicofol. The review was conducted in an open meeting held in Arlington, Virginia, on April 17, 1985. All Panel members except Dr. Richard Griesemer and Dr. Rosmarie von Rumker were present for the review.

Public notice of the meeting was published in the **Federal Register** on Friday, March 29, 1985.

In consideration of all matters brought out during the meeting and careful review of the scientific issues in connection with the review of dicofol, the Panel unanimously submits the following report:

Report of SAP Recommendations

The Scientific Advisory Panel has reviewed the dicofol Position Document 2/3 and other materials prepared by EPA, as well as materials provided by the principal registrant, Rohm and Haas Company. On the basis of this review, and the testimony presented at the April 17 meeting, the SAP would like to make the following statements:

Clearly, there are many unresolved differences between the Agency position and that of the principal registrant, differences which, in many cases, cannot be easily resolved. Given the current high DDTr levels in the compound, the recommendation in the PD 2/3 document that dicofol registrations be cancelled might well be justified on environmental grounds, despite the fact that all factors going into the proposed decision are not necessarily well founded. However, if the proposed reduction of DDTr contamination levels to 0.1 percent is implemented, then dicofol use does not appear to the Panel to represent a threat to the environment, including endangered species.

The proposed contamination reduction program, from the present level of 5.75 percent down to 2.5 percent shortly, with 0.1 percent to be reached by the Spring of 1987, is adequate and appropriate, and the Panel recommends that the Agency use this as guidance in its regulatory activities relating to dicofol.

The Panel also urges that metabolism and field studies currently underway be carried to completion at an early date.

Finally, the SAP urges that all affected parties, including EPA, the registrants, and appropriate State officials, work together to ensure that an adequate monitoring system is put in place in order that future levels and trends of DDTr in the environment may be accurately known.

For the Chairman:

Certified as an accurate report of the findings:

Philip H. Gray, Jr.,

Executive Secretary, FIFRA Scientific Advisory Panel.

Dated: April 17, 1985.

2. *COMMENTS FROM THE JULY 1985 MEETING,* Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel.

Review of the Oncogenicity Issue Being Considered by EPA in Connection with the Special Review on Dicofol.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed review of the issue of oncogenicity being considered by the Agency in connection with the Special Review of the pesticide dicofol. The review was conducted in an open meeting held in Alexandria, Virginia, on July 7, 1985. All Panel members were present for the review except for Dr. Rosmarie von Rumker. Public notice of the meeting was published in the **Federal Register** on June 21, 1985. In consideration of all matters brought out during the meeting and careful review of the scientific issues in connection with the review of dicofol, the Panel unanimously submits the following report:

Report of SAP Recommendations

The Scientific Advisory Panel has reviewed the dicofol Position Document 2/3 and other materials prepared by EPA, as well as materials provided by the principal registrant, Rohm and Haas Company. In response to the four scientific questions posed to the SAP by the Agency, each question is listed below, together with the Panel's response:

Question

1. Examining the carcinogenicity data base of dicofol alone (i.e., the NCI study, the Maronpot re-reading of the slides, the short term results, etc.) and independent of consideration of structurally related compounds, how strong is the weight-of-evidence case that dicofol is a potential human carcinogen?

Response

The SAP believes that the evidence that dicofol is a potential human carcinogen is weak.

Question

2. Given what we know about the metabolism of dicofol and related compounds (e.g., DDT and DDE), to what degree should the Agency incorporate consideration of DDT and DDE data in reaching a weight of the evidence on the potential human carcinogenicity of dicofol?

Response

Consideration of structural relationships between different compounds can be a powerful tool for determining priorities for testing, but should not be used as a basis for regulatory action. Based on existing data, there is no evidence that dicofol is metabolized to DDT, DDE, or their metabolites. Therefore, EPA should not incorporate considerations of DDT and DDE data in reaching a weight-of-evidence judgment on the potential human carcinogenicity of dicofol.

Question

3. The Science Advisory Board has noted that on the spectrum of weight of the evidence for potential human carcinogenicity a point is reached at which use of the data for a quantitative risk assessment can no longer be justified. From this perspective, is a quantitative risk assessment for dicofol justified?

Response

The Panel believes that a quantitative risk assessment for dicofol as a carcinogen cannot be justified. The SAP further suggests that such a risk assessment be omitted from dicofol documents until there are sufficient data to justify such an assessment.

Question

4. Are the methods used for estimating human exposure to dicofol appropriate for the problems at hand? How should the results of those procedures be characterized: e.g. gross overstatements, gross understatements, or reasonable estimates?

Response

In the absence of sufficient information, the Panel is unable to characterize the dietary and applicator exposure estimates. The SAP

does believe however, that more realistic dietary exposure could be derived utilizing the new Tolerance Assessment System.

For the Chairman:

Certified as an accurate report of Findings:

Philip H. Gray, Jr.,

Executive Secretary, FIFRA Scientific Advisory Panel.

Date: July 29, 1985.

E. EPA Response to Comments of the Panel

The Panel commented concerning the registrants' proposal to lower the DDTr contamination level to 0.1 percent and the resulting enivronmental impacts. EPA generally agrees with this comment that this lower DDTr contamination level will not cause unreasonable adverse effects on most non-target species. EPA, however, agrees with the OES Biological Opinion concerning the impact of the continued use of dicofol on endangered species.

EPA agrees with the Panel concerning the need for metabolism and field studies to be completed at an early date. Poultry and rat metabolism studies are nearing completion and will be finalized by December 1986. Additionally, EPA will require reproduction and metabolism tests in sensitive avian species.

In regard to the Panel's comments urging that EPA, the registrants, and State officials work together to establish systems for the monitoring of DDTr levels in the environment, EPA is receiving and examining data that are collected through monitoring programs established by Federal and State agencies. For example, California, where use of dicofol accounts for as much as one-half of the dicofol applied in the U.S., monitors annually for DDTr compounds in their inland waterways, and the U.S. Fish and Wildlife Service conducts a national monitoring program every 2 to 3 years for DDT and other organochlorine compounds in birds and fish. Also, EPA has a compliance monitoring scheme to ensure that registrants comply with the requirements for particular levels of DDTr in their dicofol products. Finally, EPA will require the registrants to conduct long-term environmental residue monitoring for dicofol.

EPA agrees with the Panel's conclusion that the evidence for the carcinogenicity of dicofol is weak. Although EPA believes that the structural similarity between dicofol and DDT, DDE, and related chemicals is a pertinent consideration, it does not change this overall conclusion concerning the weight of the evidence.

EPA also agrees with the Panel regarding the inappropriateness of conducting a quantitative risk assessment in this case and therefore the quantitative risk assessment has been omitted in favor of the qualitative one previously discussed.

F. Public Comments Received in Response to the Amended Notice

Comments were received from four respondents concerning the substance of EPA's proposed decision to continue the registration of dicofol registrations. Of these four comments, two were from the National Audubon Society and one from the National Resources Defense Council (NRDC) objecting to the proposed decision, and one from the USDA and Ohio Department of Natural Resources supporting the proposed decision. The substantive comments address four main issues: DDT and DDE contamination of the environment; monitoring of both registrants producing dicofol and the users of the end-use formulations; the classification of dicofol as a category C carcinogen; and the role of dicofol in integrated pest management in cotton.

1. *DDT and DDE contamination of the environment.* Both Audubon and NRDC argued that EPA had given inadequate weight to the facts that dicofol is contaminated with DDTr leading to further unacceptable DDTr contamination of the environment, that dicofol may possibly be metabolized or interconverted to DDE in the physical environment, that dicofol might metabolize to DDE in organisms, and that dicofol, itself, may possibly cause adverse environmental effects due to its close structural similarity to DDT.

EPA responds that in its modeling it used an average contamination level of 10 percent DDTr to determine whether there would be adverse effects to the environment. If the newly required dicofol products containing only 0.1 percent DDTr were used, this hundredfold reduction would not be expected to add appreciable amounts of DDTr to the environment and would not be likely to cause adverse effects to the environment.

EPA shares Audubon's and NRDC's concern about the possibility that dicofol might metabolize or interconvert to DDE in the environment. The available data on the metabolism of dicofol do not definitively resolve the issue of whether dicofol residues are converted to DDE in animals. EPA has a number of studies which support the conclusion that dicofol does convert to DDE, although such studies are also susceptible to other interpretations. On the other hand, there are metabolism studies which fail to indicate that dicofol is metabolized to DDE but none of these studies proves unequivocally that such conversion does not occur (see Unit III.A.8 above).

EPA has required the registrants to develop data on the environmental fate of dicofol as well as on metabolism of dicofol in other avian species. If, after such data are submitted and evaluated by EPA, dicofol is shown to convert as speculated, EPA will then reconsider its current position that dicofol with reduced levels of DDTr does not cause unreasonable adverse effects on the environment.

NRDC also commented on a report recently released by the California Department of Food and Agriculture (CDFA), entitled "Agricultural Sources of DDT Residues in California's Environment," which concluded that the source of DDTr residues in California is the previous legal use of DDT products. NRDC argues that the contribution of dicofol is not adequately assessed in this report. Additionally, the possibility of chlorinated DDT conversion to DDE in the environment should be included in a thorough assessment.

EPA has also received this report from CDFA. The report provides evidence that DDTr residues are still occurring throughout California's environment, but states that, "Contamination of other pesticides (dicofol) by DDT cannot account for the residues. . . . [O]n analysis of historical and empirical evidence, CDFA concluded that residues from legal applications of DDT, before its use was banned, appear to be the source of this contamination." In EPA's own analysis, assuming that the rate of dicofol usage remains approximately the same, it is projected that by the year 2000 the DDTr concentration within Kings County California (a county receiving some of the highest current annual loadings of dicofol) will be only about 1 percent higher than it would be if all dicofol (with 0.1 percent DDTr contamination) use had ceased in 1985. This projection assumed no environmental loading of DDTr due to environmental conversion of dicofol to DDE. If EPA's reviews of the required environmental fate studies shows that dicofol metabolizes or converts to DDE or any other DDE precursor, a new exposure assessment will be made.

Concerning the NRDC comment that CDFA does not estimate whether or not DDTr residues are higher where dicofol has been used, there have been attempts by California and Florida to measure the increase in environmental DDTr residues resulting from normal application of dicofol products. Neither

study identified a significant increase in DDTr residues. A residue increase is certainly possible, but an environmental monitoring study would have to be unusually sensitive in order to detect it. EPA will require the registrants to conduct studies to monitor the contribution of dicofol to environmental loads of DDTr.

2. *Monitoring.* EPA agrees with Audubon that dicofol monitoring is necessary. EPA will monitor the production of dicofol as Audubon proposes. The U.S. Department of the Interior is already extensively monitoring for DDT in wildlife and has been providing that information to EPA. EPA agrees with Audubon that monitoring of organisms in the place of application of dicofol is also needed to help determine if residues of DDTr are persisting or decreasing. As noted above, EPA will require such monitoring.

3. *Oncogenicity of dicofol.* NRDC objects to EPA's reliance on its "Proposed Guidelines for Carcinogenic Risk Assessment" published in the Federal Register of November 23, 1984 (49 FR 46294) for the reclassification of dicofol as a category C carcinogen. NRDC notes that the Science Advisory Board (SAB) recommended the deletion of certain criteria used for reclassifying the oncogenic response of a substance from sufficient to limited and NRDC argues that if those criteria were not considered in evaluating the data on dicofol, the evidence might be considered sufficient to support a quantitative risk assessment. The SAB recommended deleting the criteria of the occurrence of excess tumors in a single sex and the occurrence of metastases or invasion. EPA has considered this recommendation and the final draft of the guidelines will reflect the deletion of the evidence of metastases criterion. The criterion concerning the occurrence of excess tumors in a single sex was retained. Even with this revision, EPA's classification of dicofol would remain the same.

EPA has also requested additional data to help augment the basis for its reclassification. EPA required the registrants to submit mutagenicity data on dicofol.

4. *Role of dicofol in integrated pest management.* NRDC makes a number of comments concerning the use of dicofol in integrated pest management (IPM) programs. Relying on the arguments of Dr. Ted Wilson of the Entomology Department of the University of California at Davis, an expert in IPM on cotton, NRDC contends that it is an overstatement to claim that dicofol has no effect on natural predators. NRDC also quotes comments submitted to EPA by Dr. Wilson stating that, "there should be stringent restrictions on the continued use of dicofol—even with the lowered DDTr concentrations." NRDC also notes that in these comments Dr. Wilson recommended a reduced spraying schedule for dicofol.

EPA contacted Dr. Wilson about his recommendations and in general, Dr. Wilson feels that his comments were taken out of context by NRDC. Dr. Wilson indicated that dicofol will affect some predatory species, but both sulfur and propargite (possible alternatives to dicofol on cotton) would negatively impact predator populations more severely than dicofol. Specifically, Dr. Wilson indicated that one application of dicofol will reduce predatory thrips nymphs about 18 percent and have little or no effect on predatory bug populations. Predatory mites, which are generally only of significance in early spring, would also be reduced in numbers by dicofol used during that period.

Dr. Wilson also states that he did not mean to suggest that "stringent restrictions . . . on the continued use of dicofol—even with lowered DDTr concentations" were necessary or appropriate. Finally, Dr. Wilson indicated that no more than one application of dicofol is necessary on cotton in most instances, but this view is in agreement with current use practices and recommendations.

When Dr. Wilson's comments are put into context, they do not conflict with IPM decisions and goals analyzed and used in EPA's Special Review documents.

VI. Procedural Matters

This notice announces EPA's intent to cancel the registrations of products containing dicofol unless the terms and conditions of registration are modified. This unit of the notice explains how current registrants may apply to amend their registrations to comply with the terms and conditions set forth in Unit IV.

Under sections 6(b) and 3(c)(6) of FIFRA, applicants, registrants, and certain other adversely affected persons are also entitled to respond to this notice by requesting a hearing on the actions that EPA is initiating. Unless a hearing is properly requested with regard to a particular registration or application, this action will become final by operation of law.

This unit of the notice explains how such persons may request a hearing on EPA's final cancellation and denial notice (and the consequences of requesting a hearing and failing to request a hearing in accordance with those procedures).

A. Procedure for Amending the Terms and Conditions of Registration to Avoid Cancellation or Denial of Application

Registrants affected by the cancellation actions set forth in this notice may avoid cancellation by filing an application for an amended registration which contains the label modifications detailed in Unit IV of this notice. This applicaion must be filed within 30 days of receipt of this notice, or within 30 days from the publication of this notice, whichever occurs later. Applicants for a registration subject to this notice must file an amended application for registration within the applicable 30-day period to avoid denial of their pending application.

Applications must be submitted to: By mail: Lawrence J. Schnaubelt, Product Manager 12, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460, (703-557-2386).

B. Intrastate Pesticide Products

This unit of the notice explains the procedures that must be followed to file an application, or amend a pending application, for Federal registration of an intrastate product. (On December 30, 1985, EPA sent all intrastate producers a letter requiring them to submit an application for Federal registraton by June 30, 1986.) It also explains the consequences of a failure to file a proper application in a timely manner.

1. *Procedure for filing for Federal registration of an intrastate product.* EPA will allow producers of intrastate products containing dicofol to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver their products if they file a timely, proper application for Federal registration or amended application for registration. In either case, the application must conform to the requirements in Unit IV.B. of this notice. This application must be filed within 30 days of receipt of this notice, or within 30 days of publication of this notice, whichever occurs later.

Applicaitons must be submitted to: Stuart C. MacArthur, Registration Support and Emergency Response, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 30460, (703-557-2227).

Intrastate products released for shipment by the producer after June 30, 1986, must comply with the requirements

in Unit IV. This date is consistent with the deadlines established by the December 30, 1985, letter to intrastate producers requiring submission of applications for Federal registration. Compliance with these requirements does not eliminate the requirement to maintain any other restrictions on the purchase, possession, supervision, use, or dispozal on the current label of the product.

2. *Consequence of filing or failing to file a proper, timely application.* Producers of intrastate products are required to submit applications for Federal registration when so instructed by EPA (40 CFR 162.17). As long as a producer submits a timely application, he may continue to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver his products in intrastate commerce. If a producer fails to submit a timely application or amended application, EPA may take appropriate enforcement action against the producer for selling and distributing an unregistered pesticide under FIFRA sec. 12(a)(1)(A).

If the application submitted for Federal registration of an intrastate product containing dicofol does not comply with the provisions of this notice, EPA may deny the application. If EPA finally denies an application for Federal registration of an intrastate product, an distribution, sale, offering for sale, holding for sale, shipping, delivering for shipment, or receiving and (having so received) delivering or offering to deliver that product would be a violation of FIFRA and subject to possible enforcement actions.

C. Procedures for Requesting a Hearing

To contest the cancellation action set forth in this notice, Federal registrants may request a hearing within 30 days of receipt of this notice, or within 30 days from publication of this notice, whichever occurs later. Any other person adversely affected by the action described in this notice, may request a hearing within 30 days of publication of this notice in the **Federal Register**.

A registrant or other adversely affected party who requests a hearing must file the request in accordance with the procedures established by FIFRA and EPA's Rules of Practice Governing Hearings under 40 CFR Part 164. These procedures require, among other things, that all requests must identify the specific pesticide product(s) and the specific use(s) for which a hearing is requested, and that all requests must be received by the Hearing Clerk within the applicable 30-day period. Failure to comply with these requirements will result in denial of the request for a hearing. Requests for a hearing should also be accompanied by objections that are specific for each use of each pesticide product for which a hearing is requested.

Requests for a hearing must be submitted to: Hearing Clerk (A–101), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

1. *Consequences of filing a timely and effective hearing request.* If a hearing on the action initiated by this notice is requested in a timely and effective manner, the hearing will be governed by EPA's Rules of Practice for hearings under FIFRA sec. 6 (40 CFR Part 164), as modified below. The hearing will be limited to the specific uses and specific product registrations for which the hearing is requested

If the event of a hearing, the specific use or uses of the specific registered product which is the subject of the hearing will not be cancelled except pursuant to an order of the Administrator at the conclusion of the hearing.

2. *Consequences of failure to file in a timely and effective manner.* If a hearing concerning the registration of a specific pesticide product subject to this notice is not requested by the end of the applicable 30-day period, registration of that product will be cancelled, unless the registrant files a request for an amended registrations within the statutory period provided herein (see Unit VI.A).

If the registration of a product covered by this notice is cancelled by operation of law, the sale, distribution, use, and disposal of existing stocks is governed by the provisions of Unit IV.D of this notice.

D. Separation of Functions

EPA's Rules of Practice forbid anyone who may take part in deciding this case, at any stage of the proceeding, from discussing the merits of the proceeding *ex parte* with any party or with any person who has been connected with the preparation of presentation of the proceeding as an advocate or in any investigative or expert, capacity, or with any of their representatives (40 CFR 164.7).

Accordingly, the following EPA offices, and the staffs thereof, are designated as the judicial staff to perform the judicial function of EPA in any administrative hearing on this Notice of Intent to Cancel: the office of the Administrative Law Judge, the office of the Judicial Officer, the Administrator, the Deputy Administrator, and the members of the staff in the immediate office of the Administrator and Deputy Administrator. None of the persons designated as the judicial staff may have any *ex parte* communication with the trial staff or any other interested person not employed by EPA on the merits of any of the issues involved in this proceeding, without fully complying with the applicable regulations.

Dated: May 22, 1986.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

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